TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

Economic Impact Statement
LSA Document #14-338

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses
Summary of the Rule Amendment

Existing Indiana rules are outdated and not in alignment with current United States Public Health (PHS) clinical guidelines and findings from the Centers for Disease Control and Prevention (CDC). For example, Indiana currently restricts reimbursement to one (1) twelve (12) week course of smoking cessation treatment per recipient per calendar year. PHS guidelines recommend a course of treatment for up to twenty-four (24) weeks per rolling calendar year. In addition, scientific findings from the CDC demonstrate that most tobacco users require at least three (3) quit attempts per year before successfully quitting.

The proposed rule expands the Indiana Family and Social Services Administration's (FSSA) reimbursement limitation and subjects continued smoking cessation treatment to prior authorization, which means a person could receive treatment more than once a year when it is determined to be medically necessary. This change would allow clinicians to more effectively manage the utilization of medically necessary tobacco dependence drug products and counseling sessions programmatically according to clinical practice standards. Such policies and practices are consistent with the utilization of other drugs in the Indiana Medicaid pharmacy benefit and services in the medical benefit. Additionally, this rule amendment revises 405 IAC 5-37 to update definitions and expand the list of practitioners eligible to provide tobacco dependence counseling.

Impact on Small Business

The following section provides responses to the following questions outlined in IC 4-22-2.1-5:

1. An estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

IC 5-28-2-6 defines a small business as a business entity that satisfies the following requirements:

(1) On at least fifty percent (50%) of the working days of the business entity occurring during the preceding calendar year, the business entity employed not more than one hundred fifty (150) employees.

(2) The majority of the employees of the business entity work in Indiana.

The primary purpose of the proposed rule is to expand FSSA's reimbursement of tobacco dependence treatment. Thus, the proposed rule will mainly impact Medicaid fee-for-service members and MCE members including HIP and Hoosier Care Connect, particularly those members who currently use tobacco products and would like to quit. Pharmacies and providers who choose to provide tobacco dependence treatment to the aforementioned members will also be affected by the proposed rule. The proposed rule may have an impact on 162 small pharmacies, which are considered small businesses as defined in IC 4-22-2.1-4.

2. An estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

New providers who want to participate in the Medicaid program will need to become familiar with the administrative processes required for participation. For example, providers who are not already providing Medicaid services are required to pay an approximate $550 application fee and periodic renewal fees and undergo a background check. Providers also must comply with certain record retention and reimbursement claim rules and determine ways to collect copayments. These administrative processes are generally consistent with the processes required for providers under many commercial insurance plans in which they participate. Thus, the proposed rule amendment will not impose any additional annual reporting, record keeping, or other administrative costs on small businesses in order to comply with the proposed rule.

3. An estimate of the total annual economic impact that compliance will have on small businesses subject to the rule.

A new provider will treat more patients as a result of its participation in the Medicaid program. FSSA expects that any increase in provider costs will be offset by increases in revenue through reimbursement from the Medicaid program. Thus, there is no negative economic impact that compliance will have on a small business subject to this rule.

4. A statement justifying any requirement or cost that is imposed by the rule and not expressly required by law. The statement must reference any data, studies, or analyses relied upon by the agency in determining imposition of the requirement or cost is necessary.

The proposed rule does not impose any requirement or costs that are not required by law.

5. Any regulatory flexibility analysis that considers any less intrusive or less costly alternative methods of achieving the same purpose.

Other factors considered:

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The rule has no impact on reporting requirements for small businesses.

B. Establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses.

The rule has no impact on schedules or deadlines for compliance or reporting requirements for small businesses.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The rule has no impact on compliance or reporting requirements for small businesses.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

The rule has no impact on performance or operational standards for small businesses.

E. Exemption of small businesses from part or all of the requirements or costs imposed by the rule.

The rule imposes no additional requirements or cost on small businesses.

FSSA has relied upon an analysis performed by the Medicaid Medical Advisory Cabinet (MMAC). Internal Office of Medicaid Policy and Planning (OMPP) staff also performed analyses using Indiana Medicaid claims data.

If there are any programmatic or fiscal questions, please contact Emily Hancock at (317) 233-0097 or at emily.hancock@fssa.in.gov. Questions regarding any other aspect of the proposed changes should be addressed to Kim Crawford at (317) 232-1244 or at kim.crawford@fssa.in.gov.

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